

Food and Drug Administration, HHS

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in Cervidae less than 15 days before or during the hunting season.

[68 FR 26206, May 15, 2003]

§ 522.2670 Yohimbine injectable.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains either 2 or 5 milligrams of yohimbine (as hydrochloride).

(b) *Sponsor.* See 061690 in § 510.600(c) of this chapter for use of 2 milligrams per milliliter solution in dogs.

(1) *Amount.* 0.05 milligram per pound (0.11 milligram per kilogram) of body weight.

(2) *Indications for use.* To reverse the effects of xylazine in dogs.

(3) *Limitations.* For intravenous use in dogs only. Not for use in food-producing animals. Safety of use in pregnant dogs or in dogs intended for breeding has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c) *Sponsor.* See 053923 in § 510.600(c) of this chapter for use of 5 milligrams per milliliter solution in deer and elk.

(1) *Amount.* 0.2 to 0.3 milligram per kilogram of body weight.

(2) *Indications for use.* As an antagonist to xylazine sedation in free ranging or confined members of the family Cervidae (deer and elk).

(3) *Limitations.* For intravenous use only. Do not use in domestic food-producing animals. Do not use for 30 days before or during hunting season. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 8543, Feb. 16, 1993, as amended at 60 FR 57832, Nov. 22, 1995]

§ 522.2680 Zeranor.

(a) *Specifications.* Each pellet contains 12, 18, or 20 milligrams (mg) zeranol.

(b) *Sponsor.* See 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.760 of this chapter.

(d) *Conditions of use*—(1) *Beef cattle*—(i) *Amount.* 36 mg zeranol (one implant consisting of 3 pellets, each pellet containing 12 mg zeranol) per implant dose.

(ii) *Indications for use*—(A) For increased rate of weight gain and improved feed conversion in weaned beef

calves, growing beef cattle, feedlot steers, and feedlot heifers.

(B) For increased rate of weight gain in suckling calves.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in bulls intended for reproduction or in dairy animals. Do not use before 1 month of age or after weaning in heifers intended for reproduction. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Feedlot lambs*—(i) *Amount.* 12 mg zeranol (one implant consisting of 1 pellet containing 12 mg zeranol) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed conversion.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in breeding animals. Do not implant animals within 40 days of slaughter. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(3) *Steers fed in confinement for slaughter*—(i) *Amount.* 72 mg zeranol (one implant consisting of 6 pellets, each pellet containing 12 mg zeranol) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations.* Implant subcutaneously in ear only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(4) *Pasture cattle (slaughter, stocker, feeder steers, and heifers)*—(i) *Amount.* 138 mg zeranol (one implant consisting of 7 pellets, each of 6 pellets containing 20 mg zeranol and a seventh pellet containing 18 mg zeranol) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain.

(iii) *Limitations.* Implant subcutaneously in ear only. Safety and

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effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[59 FR 19639, Apr. 25, 1994; 60 FR 26360, May 17, 1995, as amended at 62 FR 61625, Nov. 19, 1997; 64 FR 46840, Aug. 27, 1999; 67 FR 6867, Feb. 14, 2002; 70 FR 6764, Feb. 9, 2005]

§ 522.2690 Zinc gluconate.

(a) *Specifications.* Each milliliter of solution contains 13.1 milligrams zinc as zinc gluconate neutralized to pH 7.0 with L-arginine.

(b) *Sponsor.* See No. 067647 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* The volume injected into each testicle is based on testicular width as determined by measuring each testicle at its widest point using a metric scale (millimeter) caliper.

(2) *Indications for use.* Intratesticular injection for chemical sterilization of 3- to 10-month-old male dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 26995, May 19, 2003]

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

Sec.

524.86 Amitraz liquid.

524.154 Bacitracin or bacitracin zinc-neomycin sulfate-polymyxin B sulfate ophthalmic ointment.

524.155 Bacitracin zinc-polymyxin B sulfate-neomycin sulfate-hydrocortisone or hydrocortisone acetate ophthalmic ointment.

524.390 Chloramphenicol ophthalmic and topical dosage forms.

524.390a Chloramphenicol ophthalmic ointment.

524.390b Chloramphenicol ophthalmic solution.

524.390d Chloramphenicol-prednisolone ophthalmic ointment.

524.402 Chlorhexidine ointment.

524.450 Clotrimazole cream.

524.463 Copper naphthenate solution.

524.520 Cuprimyxin cream.

524.575 Cyclosporine ophthalmic ointment.

524.590 Diclofenac.

524.660 Dimethyl sulfoxide ophthalmic and topical dosage forms.

524.660a Dimethyl sulfoxide solution.

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524.660b Dimethyl sulfoxide gel.

524.770 Doramectin.

524.802 Enrofloxacin, silver sulfadiazine emulsion.

524.814 Eprinomectin.

524.900 Famphur.

524.920 Fenthion.

524.960 Flumethasone, neomycin sulfate, and polymyxin B sulfate ophthalmic solutions.

524.981 Fluocinolone acetonide ophthalmic and topical dosage forms.

524.981a Fluocinolone acetonide cream.

524.981b Fluocinolone acetonide solution.

524.981c Fluocinolone acetonide, neomycin sulfate cream.

524.981d Fluocinolone acetonide, dimethyl sulfoxide solution.

524.981e Fluocinolone acetonide, dimethyl sulfoxide otic solution.

524.1005 Furazolidone aerosol powder.

524.1044 Gentamicin sulfate ophthalmic and topical dosage forms.

524.1044a Gentamicin ophthalmic solution.

524.1044b Gentamicin sulfate, betamethasone valerate otic solution.

524.1044c Gentamicin sulfate ophthalmic ointment.

524.1044d Gentamicin sulfate, betamethasone valerate ointment.

524.1044e Gentamicin sulfate spray.

524.1044f Gentamicin sulfate, betamethasone valerate topical spray.

524.1044g Gentamicin sulfate, betamethasone valerate, clotrimazole ointment.

524.1044h Gentamicin sulfate, mometasone furoate, clotrimazole otic suspension.

524.1140 Imidacloprid and ivermectin.

524.1193 Ivermectin pour-on.

524.1195 Ivermectin otic suspension.

524.1200 Kanamycin ophthalmic and topical dosage forms.

524.1200a Kanamycin ophthalmic ointment.

524.1200b Kanamycin ophthalmic aqueous solution.

524.1204 Kanamycin sulfate, calcium amphotycin, and hydrocortisone acetate.

524.1240 Levamisole.

524.1376 2-Mercaptobenzothiazole solution.

524.1443 Miconazole nitrate cream; miconazole nitrate lotion; miconazole nitrate spray.

524.1446 Milbemycin oxime solution.

524.1451 Moxidectin.

524.1465 Mupirocin ointment.

524.1484 Neomycin sulfate ophthalmic and topical dosage forms.

524.1484a Neomycin sulfate ophthalmic ointment.

524.1484b Neomycin sulfate, isoflupredone acetate, tetracaine hydrochloride, and myristyl-gamma-picolinium chloride, topical powder.